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09/319,541	08/19/99	MULLER	R 62-659-50781

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EXAMINER

SHARAREH, S

ART UNIT

PAPER NUMBER

1619

DATE MAILED:

11/22/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/319,541

Applicant(s)  
Muller et al

Examiner  
Shahnam Sharareh

Group Art Unit  
1619



☒ Responsive to communication(s) filed on Sep 1, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1, 2, 4-9, 11-13, and 15-25 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1, 2, 4-9, 11-13, and 15-25 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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**DETAILED ACTION**

The Amendment filed on September 14, 2000 has been entered. Claims 3, 10, and 14 are canceled. Claims 19-25 are added. Claims 1-2, 4-9, 11-13, 15-25 are pending.

***Response to Arguments***

1. The amendment has obviated the confusing "and/or" language in claims 1, 3, 7-8, 10, and 15. The rejection under 35 U.S.C. 112, second paragraph, as being indefinite language is withdrawn.

Amendment to claim 8 has obviated the rejection made under 35 U.S.C. 112, second paragraph. Said rejection is withdrawn.

Amendment to claims 13-14, 16 has obviated the improper antecedent basis.

2. Amendment to claim 17-18 have obviated the rejection made under U.S.C. 101. Said rejection is withdrawn.

3. Applicant's arguments in respect to the rejection made under 35 U.S.C. 102(b) as being anticipated by McClelland et al WO 94/00111 have been fully considered, and are found partially persuasive. The rejection of claims 15-16 is withdrawn, because McClelland does not specifically disclose methods of spray drying his formulation. Claims 1-2, 4- 5, 6-9, 11-13, 17, and the newly added claims 19-20 are rejected.

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Applicant argues that McClelland do not teach "spray drying" in the same manner as the present invention to produce particles having unexpectedly good flow characteristics. In response, Examiner states that the instant compositions appear to contain limitations in the form of

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"product by process". Accordingly, product by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (see MPEP 2113.)

If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe , 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case, McClelland disclose all components of the instant composition. Even though, McClelland does not specifically states that their compositions are formed by "spray drying", they indicate that their micro particles must be dried into spherical form, *page 3 lines 30-32*. Accordingly, McClelland composition inherently possess the same structure and the same functional limitations as presently claimed. Thus, claims 1-2, 4-5, 6-9, 11-13, 17, 19-20 stand rejected.

4. Applicant's arguments in respect to the rejection made under 35 U.S.C. 102(b) as being anticipated by Lang US Patent 5,006,345 have been fully considered and are found persuasive, because Lang does not teach prolonged release, spray-dried particles . Said rejection is withdrawn

5. Applicant's arguments in respect to the rejection made under 35 U.S.C. 102(e) as being anticipated by Sparks US Patent 5,505,962 have been fully considered and are found partially persuasive. The rejection of claims 15-16 is withdrawn, since Sparks does not fully disclose methods of spray drying his mixture. Claims 1-2, 5, 6-9, 11-12, 17-18, and the newly added claims 19-20 stand rejected.

Applicant argues that the instant compositions, unlike Sparks, does not have a membrane surrounding the core. This argument is not commensurate within the scope of the pending claims, because the instant claims are not limited to this characteristics. Applicant also argues that Sparks

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composition possess different releasing characteristics, and further that the Sparks process of preparing his prolonged release dosage form is costly and time-consuming. Again, these arguments are not commensurate within the scope of the pending claims because the instant claimed compositions are not limited to such characteristics. Sparks disclose compositions containing all the instant components and phases, therefore they inherently meet all functional characteristics of the instant compositions. Besides, different process of making the composition does not make the composition patentable over the cited prior art. Claims 1-3, 5, 6-9, 11-12, 17-18, and 19-20 stand rejected.

6. Applicant's arguments in respect to the rejection made under 35 U.S.C. 102(e) as being anticipated by Motta US Patent 5,662,935 have been fully considered and are found partially persuasive. The rejection of claims 13, 15-16 is withdrawn, since Motta does not fully disclose methods of spray drying his mixture. Claims 1-2, 4-9, 11-12, 17-18, and the newly added claims 19-20 are rejected.

Applicant argues that Motta uses different process of making. Examiner replies that if the product is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. The controlled release formulation of Motta comprise an active agent, a filler agent such as lactose or a polysaccharide matrix, and a triglyceride moiety to influence the hydrophilic/lipophilic properties of the composition, *claims 1, 5, 8, 17-18*. Thus, Motta meets the limitations set forth in the instant claim. Claims 1-2, 4-9, 11-12, 17-18, and 19-20 stand rejected.

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7. Applicant's arguments in respect to the rejection made under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lang US Patent 5,006,345 in view of Motta US Patent 5,662,935 have been fully considered and are found persuasive, because Lang does not teach prolonged release, spray-dried particles. Said rejection is withdrawn.

*New Grounds of Rejection*

8. Claims 1-2, 4-9, 11-13, 15-25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "wherein in case of cellulose materials these cellulose materials are cellulose derivatives" is indefinite. First, "in case of cellulose material" lacks antecedent basis. Second, it appears that the recitation of "cellulose derivatives" does not add any further limitations to cellulose material. If a polymer is of cellulose material, it is obviously a cellulose derivative. It is not clear what is meant by this limitation. Is the cellulose material an optional ingredient?

The recitation of "coherent" and "incoherent" appear to state a relative condition, without clarifying the metes and bounds of the claim. The specification does not provide adequate description of this relationship between the phases.

In claims 1-2, 4-9, 11-13, 15-25, the phrase "a matrix material-containing compound" is vague. Specifically the recitation of compound in said phrase. It is not clear if the instant claimed invention is directed to a composition comprising the instant components or is it a chemical compound?

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In claims 2, 4-9, 11-13, 15-25, the recitations of percentages do not specify what type of percentages are the intended amounts directed to? Percent weight, percent volume, etc..?

9. Claims 1-2, 4-9, 11-13, 15-20, 23-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Norling et al US Patent 5,958,458.

The instant claims are directed to prolonged release formulations comprising an excipient phase, an active substance phase and polymeric phase, wherein the formulation is prepared by spray drying.

Norling et al disclose sustain release dosage forms comprising an inert carrier selected inert diluent or fillers in combination with granulating or disintegrating agents or binding agents including cellulose derivatives, and an active substance, *col 6 lines 20-65, col 7 lines 1-65, col 9 lines 40-65, col 13 lines 40-65*. Norling et al also disclose methods of preparing his formulation employing a spray dryer, *col 17 lines 55-60*. Norlings composition is of spray-dried pellets, *col 21 lines 19-45*. Accordingly, Norling meets all limitations set forth in the instant claims.

10. Claims 1-2, 4-9, 11-13, 15-25, <sup>23-25</sup> rejected under 35 U.S.C. 103(a) as being unpatentable over Norling et al US Patent 5,958,458.

The teachings of Norling is discussed above. Although, Norling et al do not specifically teach the optional ingredient, cellulose derivatives in concentrations of 78-90%, they do teach the use of cellulose derivatives as a binding agent in the core component of their composition. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the appropriate amount of cellulose material by routine experimentation. Since using cellulose derivatives in oral dosage form is conventional, one of ordinary skill in the art would have had a


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reasonable expectation to succeed in modifying its concentration to form a sustain release dosage form that provides suitable releasing properties.

***Conclusion***

No claims are allowed. Applicant is requested to provide a copy of all pending claims in a more readable form in response to this Office Action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

*sjjs 11/13/2000*

  
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